{deleted text} shows text that was in HB0195 but was deleted in HB0195S01.

Inserted text shows text that was not in HB0195 but was inserted into HB0195S01.

DISCLAIMER: This document is provided to assist you in your comparison of the two bills. Sometimes this automated comparison will NOT be completely accurate. Therefore, you need to read the actual bills. This automatically generated document could contain inaccuracies caused by: limitations of the compare program; bad input data; or other causes.

Representative Brad M. Daw proposes the following substitute bill:

MEDICAL CANNABIS POLICY

2018 GENERAL SESSION STATE OF UTAH

Chief Sponsor: Brad M. Daw

LONG TITLE

General Description:

This bill creates a "right to try" cannabis-based treatment for terminally ill patients.

Highlighted Provisions:

This bill:

- defines terms;
- provides that an individual who possesses, distributes, or uses cannabis in a medicinal dosage form in compliance with Title 58, Chapter 85, Utah Right to Try Act, is not subject to the penalties described in Title 58, Chapter 37, Utah Controlled Substances Act; and
- describes the procedure for an eligible patient to receive a recommendation for a cannabis-based treatment from the eligible patient's physician or the eligible patient's advanced practice registered nurse.

Money Appropriated in this Bill:

None

Other Special Clauses:

None

Utah Code Sections Affected:

AMENDS:

58-37-3.6, as enacted by Laws of Utah 2017, Chapter 398

58-85-102, as enacted by Laws of Utah 2015, Chapter 110

58-85-104, as last amended by Laws of Utah 2016, Chapter 348

58-85-105, as enacted by Laws of Utah 2015, Chapter 110

ENACTS:

58-85-103.5, Utah Code Annotated 1953

Be it enacted by the Legislature of the state of Utah:

Section 1. Section **58-37-3.6** is amended to read:

58-37-3.6. Exemption for possession or distribution of a cannabinoid product or expanded cannabinoid product pursuant to an approved study.

- (1) As used in this section:
- (a) "Cannabinoid product" means a product intended for human ingestion that:
- (i) contains an extract or concentrate that is obtained from cannabis;
- (ii) is prepared in a medicinal dosage form; and
- (iii) contains at least 10 units of cannabidiol for every one unit of tetrahydrocannabinol.
- (b) "Cannabis" means any part of the plant cannabis sativa, whether growing or not.
- (c) "Drug paraphernalia" means the same as that term is defined in Section 58-37a-3.
- (d) "Expanded cannabinoid product" means a product intended for human ingestion that:
 - (i) contains an extract or concentrate that is obtained from cannabis;
 - (ii) is prepared in a medicinal dosage form; and
- (iii) contains less than 10 units of cannabidiol for every one unit of tetrahydrocannabinol.
 - (e) "Medicinal dosage form" means:

- (i) a tablet;
- (ii) a capsule;
- (iii) a concentrated oil;
- (iv) a liquid suspension;
- (v) a transdermal preparation; or
- (vi) a sublingual preparation.
- (f) "Tetrahydrocannabinol" means a substance derived from cannabis that meets the description in Subsection 58-37-4(2)(a)(iii)(AA).
- (2) Notwithstanding any other provision of this chapter, an individual who possesses or distributes a cannabinoid product or an expanded cannabinoid product is not subject to the penalties described in this title for the possession or distribution of marijuana or tetrahydrocannabinol to the extent that the individual's possession or distribution of the cannabinoid product or expanded cannabinoid product complies with Title 26, Chapter 61, Cannabinoid Research Act.
- (3) Notwithstanding any other provision of this chapter, an individual who possesses, distributes, or uses cannabis in a medicinal dosage form is not subject to the penalties described in this title for the possession or distribution of marijuana or tetrahydrocannabinol to the extent that the individual's possession, distribution, or use of the cannabis complies with Title 58, Chapter 85, Utah Right to Try Act.

Section 2. Section **58-85-102** is amended to read:

58-85-102. Definitions.

As used in this chapter:

- (1) "Advanced practice registered nurse" or "APRN" means a person who is licensed as an advanced practice registered nurse under Section 58-31b-301.
- (112) "Cannabis" means cannabis that has been grown by a state-approved grower and processed into a medicinal dosage form.
 - (12)3) "Cannabis-based treatment" means a course of treatment involving cannabis.
- [(1)] ((13)4) "Eligible patient" means an individual who has been diagnosed with a terminal illness by a physician.
- (4)5) "Health care facility" means the same as that term is defined in Section 26-55-102.

- $\left[\frac{(2)}{(5)}\right]$ "Insurer" means the same as that term is defined in Section 31A-1-301.
- [3] ([3]) "Investigational device" means a device that:
- (a) meets the definition of "investigational device" in 21 C.F.R. Sec. 812.3; and
- (b) has successfully completed the United States Food and Drug Administration Phase 1 testing for an investigational device described in 21 C.F.R. Part 812.
 - [4] (78) "Investigational drug" means a drug that:
 - (a) meets the definition of "investigational new drug" in 21 C.F.R. Sec. 312.3; and
- (b) has successfully completed the United States Food and Drug Administration Phase 1 testing for an investigational new drug described in 21 C.F.R. Part 312.
- ({8}<u>9</u>) "Medicinal dosage form" means the same as that term is defined in Section 58-37-3.6.
 - $[\frac{5}{10}]$ "Physician" means an individual who is licensed under:
 - (a) Title 58, Chapter 67, Utah Medical Practice Act; or
 - (b) Title 58, Chapter 68, Utah Osteopathic Medical Practice Act.
- (\{\frac{10}{11}\}\) "State-approved grower and processor" means a person who grows cannabis pursuant to state law and processes the cannabis into a medicinal dosage form.
 - [6] (11) "Terminal illness" means a condition of a patient that:
 - (a) as determined by a physician:
- (i) is likely to pose a greater risk to the patient than the risk posed to the patient by treatment with an investigational drug or investigational device; and
 - (ii) will inevitably lead to the patient's death; and
- (b) presents the patient, after the patient has explored conventional therapy options, with no treatment option that is satisfactory or comparable to treatment with an investigational drug or device.
 - Section 3. Section **58-85-103.5** is enacted to read:

58-85-103.5. Right to request a recommendation for a cannabis-based treatment.

- (1) An eligible patient may ask the eligible patient's physician or the eligible patient's APRN for a recommendation to try a cannabis-based treatment.
- (2) An eligible patient's physician <u>or APRN</u> may give the eligible patient a recommendation to try a cannabis-based treatment if:
 - (a) the physician or APRN believes, in the physician's or APRN's professional

judgment, that the cannabis-based treatment may provide some benefit to the eligible patient; and

- (b) the physician or APRN recommends a cannabis-based treatment to no more than 15 eligible patients at any given time.
 - (3) An eligible patient may possess and use cannabis as described in this section.
- (4) An eligible patient may obtain cannabis through an agreement between the eligible patient, the eligible patient's physician or the eligible patient's APRN, and a state-approved grower and processor that provides:
- (a) for the transfer of the cannabis from the state-approved grower and processor to the physician or APRN;
 - (b) that the physician or APRN will distribute the cannabis to the eligible patient; and
- (c) that the eligible patient has made arrangements for any excess cannabis in the eligible patient's possession to be returned to the physician or APRN for destruction in the event of the eligible patient's death.
- (5) (a) After recommending a cannabis-based treatment to an eligible patient, as described in Subsection (2), and receiving cannabis from a state-approved grower and processer as described in Subsection (4)(a), a physician or APRN may distribute up to a one-month supply of cannabis to the eligible patient.
- (b) Once an eligible patient has exhausted a one-month supply of cannabis, the eligible patient's physician or APRN may distribute up to another one-month supply to the eligible patient, so long as the eligible patient's physician or APRN continues to believe, in the physician's or APRN's professional judgment, that the cannabis-based treatment may provide some benefit to the eligible patient.
- (6) The physician or APRN shall provide an eligible patient who seeks a recommendation to use a cannabis-based treatment with an informed consent document that, based on the physician's or APRN's knowledge of the cannabis-based treatment:
- (a) describes the possible positive and negative outcomes the eligible patient could experience;
- (b) states that an insurer is not required to cover the cost of providing cannabis to the patient; and
 - (c) states that, subject to Section 58-85-105, an insurer may deny coverage for the

eligible patient.

Section 4. Section 58-85-104 is amended to read:

58-85-104. Standard of care -- Medical practitioners not liable -- No private right of action.

- (1) (a) It is not a breach of the applicable standard of care for a physician, other licensed health care provider, or hospital to treat an eligible patient with an investigational drug or investigational device under this chapter.
- (b) It is not a breach of the applicable standard of care for a physician or advanced practice registered nurse to recommend a cannabis-based treatment to an eligible patient under this chapter, or a health care facility to aid or assist in any way an eligible patient's use of cannabis.
- (2) A physician, other licensed health care provider, or hospital that treats an eligible patient with an investigational drug or investigational device under this chapter, or a physician or advanced practice registered nurse who recommends a cannabis-based treatment to an eligible patient or a health care facility that facilitates an eligible patient's {physician-recommended}recommended use of a cannabis-based treatment under this chapter, may not, for any harm done to the eligible patient by the investigational drug [or], device, or cannabis-based treatment, be subject to:
 - (a) civil liability;
 - (b) criminal liability; or
 - (c) licensure sanctions under:
 - (i) for a physician:
 - (A) Title 58, Chapter 67, Utah Medical Practice Act; or
 - (B) Title 58, Chapter 68, Utah Osteopathic Medical Practice Act;
- (ii) for the other licensed health care provider, the act governing the other licensed health care provider's license; or
- (iii) for the hospital <u>or health care facility</u>, Title 26, Chapter 21, Health Care Facility Licensing and Inspection Act.
 - (3) This chapter does not:
- (a) require a manufacturer of an investigational drug or investigational device to agree to make an investigational drug or investigational device available to an eligible patient or an

eligible patient's physician;

- (b) require a physician or advanced practice registered nurse to agree to:
- (i) administer an investigational drug to an eligible patient under this chapter; [or]
- (ii) treat an eligible patient with an investigational device under this chapter; or
- (iii) recommend a cannabis-based treatment to an eligible patient; or
- (c) create a private right of action for an eligible patient:
- (i) against a physician, advanced practice registered nurse, or hospital, for the physician's or hospital's refusal to:
 - (A) administer an investigational drug to an eligible patient under this chapter; [or]
 - (B) treat an eligible patient with an investigational device under this chapter; or
 - (C) recommend a cannabis-based treatment to the eligible patient; or
- (ii) against a manufacturer, for the manufacturer's refusal to provide an eligible patient with an investigational drug or an investigational device under this chapter.

Section 5. Section **58-85-105** is amended to read:

58-85-105. Insurance coverage.

- (1) This chapter does not:
- (a) require an insurer to cover the cost of:
- (i) administering an investigational drug under this chapter; [or]
- (ii) treating a patient with an investigational device under this chapter; or
- (iii) a cannabis-based treatment; or
- (b) prohibit an insurer from covering the cost of:
- (i) administering an investigational drug under this chapter; [or]
- (ii) treating a patient with an investigational device under this chapter[-]; or
- (iii) a cannabis-based treatment.
- (2) Except as described in Subsection (3), an insurer may deny coverage to an eligible patient who is treated with an investigational drug or investigational device, for harm to the eligible patient caused by the investigational drug or investigational device.
 - (3) An insurer may not deny coverage to an eligible patient under Subsection (2) for:
 - (a) the eligible patient's preexisting condition;
- (b) benefits that commenced before the day on which the eligible patient is treated with the investigational drug or investigational device; or

(c) palliative or hospice care for an eligible patient that has been treated with an investigational drug or device, but is no longer receiving curative treatment with the investigational drug or device.

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Legislative Review Note

Office of Legislative Research and General Counsel}